Certificate Under 37 C.F.R. § 3.73(b)

Applicant: Avigdor Lev

Application No.: 08/889,825 Filed: July 8, 1997

Entitled: Radiating Device for Hyperthermia

AIDA Engineering Ltd., a corporation,

certifies that it is the assignee of the entire right, title and interest in the patent application identified above by virtue of either:

A . [ ] An assignment from the inventor(s) of the patent application identified above.

OR

B. [XX] A chain of title from the inventor(s), of the patent application identified above, to the current assignee as shown below:

1. From: Avigdor Lev
To: Fondazione Centro S. Raffaele Del Monte Tabor
The document was recorded in the Patent and Trademark Office at Reel 7043, Frame 074-75.

2. From: Fondazione Centro S. Raffaele Del Monte Tabor
To: AIDA Engineering Ltd.
A copy of the document is attached and is being recorded in the Patent and Trademark Office simultaneously herewith.

[ ] Copies of assignments of other documents in the chain of title are attached.

The undersigned has reviewed all the documents in the chain of title of the patent application identified above and, to the best of undersigned's knowledge and belief, title is in the assignee identified above.

The undersigned (whose title is supplied below) is empowered to sign this certificate on behalf of the assignee.

I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and further, that these statements are made with the knowledge that willful false statements, and the like so made, are punishable by fine or imprisonment, or both, under Section 1001, Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: 4 March 1998

Name: Dr. Avigdor Lev

Title:

Signature: ____________________

Patent Transfer Agreement

Between: Fondazione Centro San Raffaele del Monte Tabor (San Raffaele)
Address : Via Olgettina, 60, Milano Italy
represented by its President, Reverend Professor Luigi Maria Verzè

and: AIDA Engineering Ltd. (AIDA)
Address: Chancery House, High Street, Bridgetown, Barbados, West Indies
represented by Dr. Avigdor Lev

Preamble

San Raffaele owns patents and patent applications listed in the Attachment A and inventions related to medical treatments as disclosed in the patents and patent applications listed in the Attachment A (the Inventions) and the relative know how.
In order to transfer the full propriety of the Inventions to AIDA, or to a third party nominated by AIDA under whatever title, the parties agree on the following :

Article 1
San Raffaele sells and assigns to AIDA, its lawful successors and assigns, or to a third party nominated by AIDA under whatever title, the entire rights, titles and interests to the Inventions, and all divisional and continuation applications, all extensions, renewals and reissues thereof, and all rights to claim priority thereon, and all patent applications that may hereafter be filed for the Inventions in any country, and all patents that may be granted on the Inventions in any country, and all extensions, renewals and reissues thereof (hereafter "the Patent Documents").

Article 2
San Raffaele represents and assures that it owns title and rights on the Inventions and on the Patents Documents, that it did not put them as guaranty or security for anything, and that it has the right to transfer them under this Agreement, and will not enter any other conflicting agreement.
San Raffaele, anyway, accepts to pay any possible future expense to extinguish any act which could put the Inventions and the patent Document as guaranty or security for anything.

Article 3
San Raffaele represents and assures that it has taken all necessary steps and paid all fees to maintain the patent Documents through the execution data of this Agreement. San Raffaele commits itself to advise AIDA or a third party nominated by AIDA under whatever title, in writing, of all necessary steps and fees required to maintain the Patent Documents from the signature of this Agreement.

Article 4
San Raffaele will not claim any interest in any modification or improvement of the Inventions by Dr. Lev, AIDA and/or any third party by them delegated under whatever title.

Article 5
San Raffaele will transfer to AIDA or to a third party nominated by AIDA under whatever title, all the technical documentation and information in possession of San Raffaele related to the Inventions. the transfer will start on same moment of the payment specified in Article 7.1.1., which times will be at the discretion of AIDA or the third party, following reasonable notice to San Raffaele.

Article 6
At the moment of the payment specified in Article 7.1.1., San Raffaele will :

- give all documents related to the execution of the patent transfer, duly compiled and signed, to activate the immediate property transfer of the Inventions to AIDA or to a third party nominated by AIDA under whatever title.
- send an irrevocable letter to all the suppliers, producers etc. involved in activities connected to the Inventions, and formerly commited with San Raffaele with a confidentiality and exclusivity agreement, where San Raffaele will inform them about the conveyance of full property on the Inventions to AIDA or to a third party nominated by AIDA under whatever title. Consequently that letter will transfer any commitment to secrecy and exclusivity taken with San Raffaele to AIDA or to a third party nominated by AIDA under whatever title.

San Raffaele promises to cooperate with and assist AIDA or a third party nominated by AIDA under whatever title, in completing the transfer of the Patent Documents and in obtaining the Patent Documents. San Raffaele will give AIDA or a third party nominated by AIDA under whatever title, all files concerning the Patent Documents in the moment of the payment specified in Article 7.1.1.
In case of future necessities, even if arisen after the payment, San Raffaele commits itself to sign any document or to take any necessary action to transfer rights and property or to evidence the transfer thereof.

Article 7
AIDA or a third party nominated by AIDA under whatever title, agrees to pay San Raffaele according to following articles :

Article 7.1.1.
Lit 500.000.000 (Hundred Millions Italian Lira) within 90 after the signature of the Agreement.

Article 7.1.2
AIDA, or a third party nominated by AIDA under whatever title, agrees to pay to San Raffaele for each system known as Urothermer or Synergo, sold by AIDA or by a third party nominated by AIDA under whatever title, the amount of USD 4,000, until a total payment of USD 800,000 (eight hundred thousands United States of America Dollars). AIDA, or a third party nominated by AIDA under whatever title, agrees to give San Raffaele, within sixty days following the end of each calendar quarter, a report of the number of systems known as Urothermer or Synergo sold and all monies due to San Raffaele. Once the payments called for by Articles 7.1.1. and 7.1.2. are made, San Raffaele shall not be entitled to any further amounts.

Article 7.2
AIDA, or a third party nominated by AIDA under whatever title, agrees to maintain records regarding the numbers of sales of the systems, as definied in art. 7.1.2 , including the serial numbers of the systems, and San Raffaele shall have the right to audit records of AIDA, or a third party nominated by AIDA under whatever title, regarding sale of the system. Committment to show records and to inform San Raffaele about sales will end when the total payment, as shown in articles 7.1.1 and 7.1.2, will be settled.

Article 8
San Raffaele promises not to assist third parties in attacks or challenges to the Patent Documents.

Article 9
AIDA, or a third party nominated by AIDA under whatever title, grants to San Raffaele a not exclusive, not-transferable license under the Patent Documents to use the Inventions solely for research purposes or treatment of patients at San Raffaele, but not for the commercial benefit of any third party.

Article 10
From the signature of this agreement, for the future, San Raffaele will grant AIDA, or a third party nominated by AIDA under whatever title, the possibility to continue seeing case files and clinical data regarding patients who underwent treatment with the system known as Urothermer or Synergo, and to cooperate with medical doctors of San Raffaele for clinical and scientifical purposes.

Article 11
This is the entire agreement between the parties regarding the transfer of full property of the applications listed in Attachment A (the Inventions) and patents to AIDA, or to a third party nominated by AIDA under whatever title, and substitutes any conflicting agreements.

Article 12
This Agreement will be interpreted under U.S.A. law as appliable to transactions completed in the Commonwealth of Massachusetts

AL

EL

Article 13
Within 90 days from the signature of this agreement, AIDA will have the right to withdraw present agreement, with unilateral decision, with no penalties.

Article 14
San Raffaele confirms its satisfaction for terms and conditions of present agreement.

Fondazione Centro San Raffaele
del Monte Tabor
Via Olgettina, 60, 20132 Milano, Italy

Signed : _____
Sac. Prof. Luigi Maria Verzè

Date: _____

AIDA Engineering Ltd.
Chancery House, High Street, Bridgetown,
Barbados West Indies

Signed : _____
Dr. Avigdor Lev

Date: _____

Article 13
Within 90 days from the signature of this agreement, AIDA will have the right to withdraw present agreement, with unilateral decision, with no penalties.

Article 14
San Raffaele confirms its satisfaction for terms and conditions of present agreement.

Fondazione Centro San Raffaele
del Monte Tabor
Via Olgettina, 60, 20132 Milano, Italy

Signed : _____
Sac. Prof. Luigi Maria Verzè

Date: 12/6/97

AIDA Engineering Ltd.
Chancery House, High Street, Bridgetown,
Barbados West Indies

Signed : _____
Dr. Avigdor Lev

Date: 17/6/97

#4

PATENT
Attorney Docket No. 6530.0060

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:	)	
U.S. Patent No.: 5,431,648	)	
Inventor: Avigdor LEV	)	**ATTN: BOX MISSING PARTS**
Issued: July 11, 1995	)	Art Unit: 3309
Serial No.: 08/889,825	)	Examiner: Not Assigned
Reissue Filed: July 8, 1997	)	
For: RADIATING DEVICE FOR HYPERTHERMIA	)	

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

RESPONSE TO NOTICE TO FILE
MISSING PARTS OF APPLICATION

In response to the communication dated September 24, 1997, Applicant submits herewith a check for the missing parts fee of $130.00, together with a copy of the Notice of Missing Parts. Also enclosed is the Assent of Assignee and the Declaration of Avigdor Lev.

To the extent any extension of time under 37 C.F.R. §1.136 is required to obtain entry of this response, such extension is hereby requested. If there are any fees due under 37 C.F.R. §§ 1.16 or 1.17, which are not enclosed, including any fees required for an extension of time under 37 C.F.R. § 1.136, please charge those fees to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: _____
Doris Johnson Hines
Reg. No. 34,629

Date: March 18, 1998

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69558 U.S. PTO
08/889825
07/08/97

PATENT
Attorney Docket No. 6530.0060

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:

U.S. Patent No.: 5,431,648

Inventor: Avigdor Lev

Issued: July 11, 1995

Serial No.: Unassigned

Filed: Concurrently Herewith

For: RADIATING DEVICE FOR HYPERTHERMIA

Attention:
Assignment Search Branch

Group Art Unit: Unassigned

Examiner: Unassigned

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

REQUEST FOR CERTIFIED ABSTRACT OF TITLE

Applicant respectfully requests that a certified abstract of title for U.S. Patent No. 5,431,648, issued July 11, 1995, be placed in the official file of the above-captioned reissue application.

Enclosed is a check in the amount of $25.00 covering the fee for this service set forth at 37 C.F.R. § 1.19(b)(4). If the enclosed payment for the order for a certified title report is for any reason insufficient, the Commissioner is hereby authorized to charge any necessary fees (and credit any overpayment) to our Deposit Account No. 06-0916.

09/19/1997 EKURTZ 00000057 08889825
01 FC:570 25.00 OP

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW, GARRETT & DUNNER, L.L.P.

By: _____
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Date: July 8, 1997

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July 8, 1997

ATTORNEY DOCKET NO. 6530.0060

Box Patent Application
Assistant Commissioner for Patents
Washington, D.C. 20231

Re: Reissue Application of U.S. Patent No. 5,431,648
Inventor: Avigdor Lev
Issued: July 11, 1995
Title: RADIATING DEVICE FOR HYPERTHERMIA

Sir:

We enclose the following papers for filing in the United States Patent and Trademark Office in connection with the above reissue application.

1. Application - 23 pages, including 18 independent claims and 79 claims total, a title page, and an Abstract;

2. Drawings - 4 sheets of drawings (Figs. 1-6);

3. Request for Certified Abstract of Title;

4. Offer to Surrender Original Patent;

5. A check for $3,428.00 representing a $770.00 reissue filing fee, a $1,298.00 extra claims fee (number of claims in the reissue application in excess of twenty (79) - 20 = 59 x $22.00), a $1,360.00 extra independent claims fee (number of independent claims in the reissue application (18) - number of independent claims in the patent (1) = 17 x $80.00); and

6. A check for $25.00 fee for certified abstract of title.

This broadening reissue application is being filed under the provisions of 37 C.F.R. § 1.53(d). Applicant awaits notification from the Patent and Trademark Office of the time set for filing the Oath or Declaration.

Please accord this reissue application a serial number and filing date.

The Commissioner is hereby authorized to charge any additional filing fees or claim fees due and any other fees due under 37 C.F.R. § 1.16 or § 1.17 during the pendency of this application to our Deposit Account No. 06-0916.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: _____
Doris Johnson Hines
Registration No. 34,629

DJH/cd
Enclosures

PATENT
Attorney Docket No. 6530.0060

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:

U.S. Patent No.: 5,431,648

Inventor: Avigdor Lev

Issued: July 11, 1995

Serial No.: Unassigned

Filed: Concurrently Herewith

For: RADIATING DEVICE FOR HYPERTHERMIA

Group Art Unit: Unassigned

Examiner: Unassigned

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

OFFER TO SURRENDER ORIGINAL PATENT

Pursuant to 37 C.F.R. § 1.178, Applicant hereby offers to surrender the original patent. The original patent, or an affidavit or declaration as to loss or inaccesability of the original patent, will be submitted before the reissue application is allowed.

Respectfully submitted,

FINNEGAN, HENDERSON, FARABOW,
GARRETT & DUNNER, L.L.P.

By: _____
Doris Johnson Hines
Registration No. 34,629

Date: July 8, 1997

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Attorney Docket No. 6530.0060

U. S. Reissue Application

of

U.S. Patent No. 5,431,648, Issued July 11, 1995

Inventor: Avigdor Lev

Title: RADIATING DEVICE FOR HYPERTHERMIA

RADIATING DEVICE FOR HYPERTHERMIA

BACKGROUND OF THE INVENTION

This invention concerns a radiating device for hyperthermia and, more particularly, a radiofrequency radiating device, for hyperthermal treatment of tumors of the bladder.

Devices for hyperthermal treatment of various human body illnesses are already known, and they use heating liquids, light radiations, radiofrequency antennas, thermistors, and so on.

U.S. Pat. No. 4,776,334 describes a catheter for treating tumors by inserting within the tumor to be treated a radiofrequency device provided with temperature sensors.

French patent application 2600205 concerns an apparatus for light irradiation of a cavity with the help of an inflatable balloon and of light sensors.

In U.S. Pat. No. 4,154,246 there is described a radiofrequency resonating circuit which is introduced in natural cavities of the body or directly inserted into the tumoral mass.

German patent application No. 2,848,636 claims usage of a heated liquid which is circulated in a closed loop by means of a pump within a body cavity, wherein the liquid temperature is controlled by an external thermostat EP-A-0 370 890 discloses a radiating urathral device for hyperthermia including a catheter provided with an inflatable balloon and adapted to receive one or more liquid flows passing therethrough, a radiofrequency radiating antenna, and one or more thermocouples, the radiating antenna being submerged within one said liquid flow coming back from the closed terminal end of the antenna. The radiating device comprises in addition a separate rectal control means.

GB-A-2 045 620 relates to an applicator for hyperthermia comprising a rectal radiating probe and a spaced apart transurethral catheter including a temperature sensing means and an inflatable balloon. U.S. Pat. No. 4,957,765 discloses a transurethral radiating applicator for hyperthermia including a multi-tubes balloon type catheter comprising closed and cubes respectively surrounding a helical coil antenna and a temperature sensor, as well as a passive drainage tube for urine.

It is an object of this invention to provide a device for hyperthermal treatment of tumors within natural cavities of the human body, which gathers the advantages of the known devices while being free from their drawbacks.

SUMMARY OF THE INVENTION

The device according to this invention substantially comprises a flexible triple path catheter carrying a radiofrequency radiating antenna, sealingly sheathed together with the shielded cable providing power supply and with several thermocouples within a plastic casing and surrounded by a flow of liquid; a second path carries the power supply cables for several outer thermocouples, which are flooded by return flow of said liquid, and a third path allowing a fluid to flow through in order to inflate a balloon located near the catheter distal end, once the latter has been introduced into the cavity to be treated.

This invention will be described more particularly in the following based on a specific embodiment thereof reported herein for exemplary and non limiting purposes, as well as on the attached schematic drawings. In

connection with the above it should be pointed out that in said drawings the parts shown are not to scale and the mutual dimensions are out of proportion, the members having in fact a very thin cross-section.

BRIEF DESCRIPTION OF THE DRAWINGS

FIG. 1 shows schematically, in an enlarged scale, the distal end of the device according to this invention, which has to be introduced into a natural cavity of the human body;

FIG. 1A shows an enlarged schematic cross-section of the device according to this invention, taken along line A—A of FIG. 1;

FIG. 2 is a schematic of some structural details of a radiofrequency antenna shown in general within the device of FIG. 1;

FIG. 2A shows a schematic enlarged cross-section of the radiating antenna, taken along line A—A of FIG. 2;

FIG. 3 is a schematic of the proximal end of the device according to this invention, opposite to the distal end shown in FIG. 1;

FIG. 4 is a plot of the intensity of the radiation generated by the radiating antenna of FIG. 2, along the longitudinal axis thereof;

FIG. 5 shows schematically the distal end of the device of FIG. 1, as it is seen after having been introduced into a urinary bladder; and

FIG. 6 shows schematically the structure at the distal end of the device shown in FIG. 1, when ready for introduction into the organ to be treated.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

The device according to this invention has a shape and consistency of a flexible catheter whose distal end, as it is shown in FIG. 1, encloses therewithin an antenna 1 surrounded by a flow of liquid 2 which is introduced into the bladder through an opening 3 and, after being freely circulated within said bladder, is again sucked into the catheter through an opening 4. Said opening 4 is in communication with a second way or catheter side channel 5 housing the leads of several thermocouples, like for instance 6, 6', 6'' adapted to be deflected outwards by inflating a balloon 7 in which a gaseous fluid or a liquid is made to flow through a third path or side channel 8 and through an end opening 9.

The catheter opposite (proximal) end (FIG. 3) whose tip is shown in FIG. 1, has three diverging inlets corresponding to the three paths or channels 2, 5, 8 of said catheter. Within center inlet 10 there is inserted with a pressure fit a plug 11 provided with a center through passage and with a side branch 13; in center passage 12 of plug 11 there is in turn pressure fitted a second plug 14 which is provided as well with a center opening 15. Shielded cable 16 supplying power to antenna 1 runs through the center passages 12 and 15 of said two coaxially arranged plugs, while side branch 13 is provided as an inlet and an outlet of a conditioning fluid flowing along channel 2. Thermocouple power supply cables 6, 6', 6'' are laid through side entrance 17 provided with a branch 18, and they run along side path or channel 5 having said conditioning liquid flowing in a reverse direction therethrough, said liquid entering and exiting in turn through said branch 18. The other side entrance 19 is provided with a one-way valve 20 for introducing the fluid that, flowing along second side channel 8, is used to inflate balloon 7.

Slightly downstream from said three entrances 10, 17, 19 there is provided, in a sleeve-like fashion and in intimate contact around the catheter body, a heat exchanger 31, operated in a known fashion from outside, and used to cool or to heat said conditioning liquid flowing through central channel 2 and coming back through side channel 5, or viceversa.

Referring now to FIGS. 2 and 2A, radiating antenna 1 will be described more in detail; the useful radiating portion of linear dipole antenna 1 comprises a terminal coil-shaped segment 21 of central conductor 22 which, immediately upstream from coil 21 is tightly surrounded, in sequence, by a first plastic inner sleeve 23, by a metal braiding 24, by a second intermediate plastic sleeve 25, by a metal cylinder 26 electrically connected with shield 24, and eventually by an outer plastic sleeve 27.

Immediately beneath sleeve 27 there is provided the power supply cables for several thermocouples located in a way suitable to detect the operating temperatures in predetermined positions of the antenna and of the power supply cable thereof. For instance, a first thermocouple 28 may be located in the position of the stretch of catheter which will be located at the prostatic urethra when the catheter with its antenna are inserted within the bladder; a second thermocouple 29 slightly upstream from antenna 1, at the bladder neck, while a third thermocouple 30 is located close to central conductor 22, between metal cylinder 26 and end coil 21, after having been wrapped with one or more coils around shield 24 immediately upstream from intermediate sleeve 25 and metal cylinder 26, and a second time, with a larger number of coils, around the stretch of central lead 22 projecting out of metal cylinder 26 before winding up to form end coil 21, the stretch of thermocouple 30 power supply cable connecting said two points being inserted with intimate contact between intermediate sleeve 25 and metal cylinder 26.

In any case, the end stretches of the power supply cables, immediately ahead of the thermocouples, are wrapped in a number of helical coils in order to increase the thermal capacity and the radiofrequency resistance of the ends which are designated to detect the temperature, while reducing to a minimum, or completely avoiding the dispersive thermal conduction along said cables.

In FIG. 1A, which shows schematically a cross-section of the catheter according to this invention, taken in any position of the stretch going from heat exchanger 31 to intermediate sleeve 25, there is shown side channel 5 carrying the power supply cables of thermocouples 6, 6', 6'' and side channel 8 for the flow of the fluid used to inflate balloon 7, both said channels 5 and 8 being managed within the thickness of the actual catheter whose inner bore 2 intended for the flow of the conditioning liquid carries, in a central position, shielded cable 16 comprised of central conductor 22, inner sleeve 23, shield 24 and outer sleeve 27, as well as inner thermocouples 28, 29 and 30 power supply cables (not shown).

FIG. 2A is a schematic cross-section of antenna 1, taken along line A—A of FIG. 2. The following are shown therein, starting from the center: conductor 22, inner sleeve 23, metal shield 24, an intermediate sleeve 25, a metal cylinder 26, and outer sleeve 27, as well as thermocouple 30 power supply conductor.

FIG. 4 is a diagram showing the radiation intensity starting from the coil-shaped end 21 of antenna 1 towards shielded power supply cable 22, 16. As it is

shown, intensity is a maximum when passing from radiating coil 21 to the stretch protected by metal cylinder 26, and it tends to nil at the position of shielded cable 16.

There is shown schematically in FIG. 5 the longitudinal section of the catheter provided with a radiating antenna according to this invention, once it has been introduced into the bladder, in an operative condition. The catheter, carrying the radiating antenna therewithin, is introduced into bladder 32 through the urethra, in such a way that the rear end of protective metal cylinder 26 is located approximately at the bladder neck, in the transition area between prostata 33 and bladder 32, while simultaneously taking care that the catheter front end does not subject the bladder internal wall to any pressure. Once the catheter has been introduced into the bladder in such a way, one actuates the supply pump of conditioning liquid 2 preferably comprising a solution of a selective citotoxicity substance, which is accordingly forced to circulate through the bladder coming out from opening 3 and going back through opening 4, or viceversa, along side channel 5 which carries the power supply cables of thermocouples 6, 6', 6'' therewithin. The liquid forced circulation, provided by the variable flowrate supply pump, suitably combined with an outer balancing and degassing chamber, allows the volume of liquid within the bladder to be balanced at will, in such a way as to compensate the pathological or physiological urine production, while thoroughly ejecting the gases generated or unwillingly introduced in circulation, out of the bladder, in order to prevent irradiation non-uniformities which would otherwise be caused by coexistance of anisotropic media. Once bladder 32 has been completely filled with conditioning liquid 2, ballon 7 is inflated by introducing a fluid, which may be a gas but it is preferably a liquid, along side channel 8 and through the end opening 9 thereof; ballon 7 inflated as mentioned above, pushes then against outer thermocouples 6, 6', 6'' power supply cables thereby moving said thermocouples into tangential engagement against bladder wall 32 in different positions, in order to detect the temperatures prevailing therein as caused by irradiation generated by antenna 1. The possibility of changing the location and the number of the outer thermocouples, enables the thermocouples to be positioned at will, on the bladder wall, or in any case of the body organ to be treated, while being able to individually check the temperatures in the various locations. The inflated ballon 7 protects the bladder neck wall from an excess heat caused by the proximity of the radiating antenna, and in the meantime it prevents the catheter from being accidentally displaced or from coming out through the bladder neck.

The dimensions of antenna 1 are such that it may be freely positioned along the catheter while being obviously wholly contained within the human bladder to be treated, but in the meantime they must be suitable to generate a therapeutically active radiation, in order to reach the temperatures considered lethal for the cancer cells. Since the physical length of an antenna is related to the virtual electrical length thereof through an equation involving the impedence of said antenna, as well as the impedence deriving from the environment irradiated by the antenna, the antenna electrical length comes out to be inversely proportional to the irradiated medium conductivity. Accordingly, since the conductivity of an aqueous solution is for instance many times higher than the conductivity of air, when operating in an aqueous environment it is possible to use an antenna which is

physically quite shorter than the length needed if it were necessary to operate in air.

The dipole according to this invention corresponds to a dipole of the quarter wave type and in the aqueous environment comprising the solution filled bladder, it makes it possible to operate at frequencies in the range of 900–1000 MHz; in particular, a frequency of 915 MHz has been chosen since very different frequencies would result in penetration, intensity, and other effects not always exactly predictable and controllable in the body tissues, since in general high frequencies have a low penetration power and therefore they do not provide the desired local heating, while lower frequencies, having a higher penetration power, may get deeper tissues involved and damaged.

On the other hand, radiations having different wavelengths might create a disturbance for radio and telephone communications, protected by constraints imposed by the legislations of the various countries.

In order to reduce to a minimum and possibly to nil the influence of the radiofrequency field on the thermocouples, as well as the various thermoelectric effects connatural with said thermocouples, the supply cable end stretches close to the thermocouples are wound into an helical shape whereby the temperature measured in the various sensing points is a reliable data, unaffected by said influences. The above structure construction prevents measuring errors due to conduction, it provides a reliable temperature indication, for instance exactly in the area of the dipole power supply position in the case of thermocouple 30, and it reduces in an extremely effective manner the thermocouple self-heating process due to radiofrequencies, also when there is an extremely high concentration of energy, whereby said structures are almost unaffected by the disturbances in the radio-frequency field.

Since the sizes, and in particular the cross-sections of the plural device components according to this invention must be extremely small, to suit the particular field of use desired for the device, the energy losses due for instance to self-heating of the antenna power supply cable are particularly high, for instance in the range of 20–40%. Since this undesirable self-heating, due to the Joule effect, might cause excessive heating of the urethral walls, and accordingly a discomfort for the patient subjected to treatment, or even damages to the tissues, the antenna cable, and the antenna itself are continuously cooled, while in operation, by using the conditioning liquid flow directed to the bladder and then withdrawn again therefrom, whereby a simultaneous control action is obtained, for controlling the temperature prevailing both in the liquid within the bladder and along the urethra. Temperature control is effected by variations of the conditioning liquid supply flow and of the cooling source temperature. In such a way it is possible both to increase the temperature and to withdraw heat.

In order to enable outer thermocouples 6, 6', 6'' for detecting the bladder wall temperature to be safely deflected outwards when balloon 7 is inflated, the power supply cables thereof are reinforced along their whole length by inserting within the protecting sheath thereof a thin stainless steel wire providing them with the required rigidity and flexibility. The presence of said reinforcing wire provides as well he thermocouple power supply cables with the mechanical strength necessary to bear the compressive and tensile stresses caused when the cables are inserted within side channel

5, and when thermocouples 6, 6', 6'' are laid in the desired locations.

When the catheter, provided with all its components, is introduced into the urethral channel, all the way to the bladder, the ends of outer thermocouples 6, 6', 6'' projecting upstream of balloon 7 through opening 4 are temporarily locked by inserting them, downstream of balloon 7, in one or more notches provided, as the case may be, in suitable positions according to the different body organ or the particular patient to be treated, close to the catheter end, as it is shown in FIG. 6. When balloon 7 is inflated it causes the thermocouple ends to come out from the notches and then to deflect outwards until the thermocouple tips come into engagement with the bladder wall. The particular outwards deflecting system of thermocouples 6, 6', 6'' causes the ends of the respective power supply cables comprising the actual thermocouple, to tangentially engage the bladder wall, whereby no excessive concentrated pressures are generated. On the other hand, the tangential position taken by the thermocouple tips when contacting the bladder wall, makes it possible to measure the actual temperature of the wall position considered in that at the boundary between said wall and the liquid filling the bladder there is a thin liquid layer substantially stationary, which is not affected by the liquid circulation within the bladder, since it clings to the tissue because of a physical attraction, while the coil shape of the cable terminal stretches increases the thermal capacity of the thermocouple whose diameter, inclusive of the coils, is less than 0,7 mm whereby the thermocouple is completely submerged within the liquid stationary layer having a thickness of approximately 1 mm.

After the thermocouples have been deflected outwards within the bladder, it is still possible to modify their location by performing pushing and/or pulling actions on the reinforced power supply cables, as mentioned above, and possibly by rotating the catheter containing them. Control of the temperature detected on the bladder walls and/or within the circulating liquid mass, is obtained by changing the flowrate of said liquid from few cubic centimeters per minute to several tens of cubic centimeters per minute. The circulated fluid circulating system prevents permanence or formation and build-up of possible gas bubbles within the bladder or through the circuit, in that air or other gas bubbles having possibly formed or being already present, are entrained out by the continuous flow and exhausted to the outer environment in an appropriate position of the outer pumping circuit. In addition, the liquid circulation provided as above presents the antenna and the environment thereof from overheating, therefore from causing undesirable reactions within the circulating liquid.

It is pointed out herein that all the antenna and thermocouple components contacted by the liquid circulating within the bladder are sealingly lined and insulated from the outer environment by a polytetrafluoroethylene layer whereby, after each usage and application they may be sterilized for subsequent further use.

We claim:

1. (Amended) A radiating device for [urethral] hyperthermia including a catheter provided at its distal end with an inflatable balloon (7) and adapted to receive multiple injected liquid fluid flows (2,5,8) passing therethrough, a radiofrequency radiating antenna (1) and multiple thermocouples (6,6',6"), the radiating antenna being submerged within [said] a fluid flow, characterized in that

said radiating antenna (1) is submerged within a flow which proceeds through a central channel (2) surrounding said radiating antenna (1) towards the distal end of said catheter and passes from said catheter through a first opening (3) into [the] a bladder to be treated, while flowing back into said catheter towards the proximal end thereof through a second separate opening (4) of a side channel (5) surrounding the power supply cables of said thermocouples (6,6',6"),

the ends of said thermocouples (6,6',6") project out of said second opening (4), being thus deflected outwards into the bladder when said balloon (7) is inflated by injecting a fluid through a second side channel (8) and third opening (9), whereby the outwardly deflected ends of said thermocouples (6,6',6") come into tangential engagement with [the] a bladder wall (32) irradiated by said antenna (1).

2. A radiating device including a catheter provided at its distal end with an inflatable balloon and adapted to receive multiple injected liquid fluid flows passing therethrough, a radiofrequency radiating antenna and multiple thermocouples, the radiating antenna being submerged within a fluid flow, characterized in that

said radiating antenna is submerged within a flow which proceeds through a central channel surrounding said radiating antenna towards the distal end of said catheter and passes from said catheter through a first opening into an organ to be treated, while flowing back into said catheter towards the proximal end thereof through a second separate opening of a side channel surrounding the power supply cables of said thermocouples,

the ends of said thermocouples project out of said second opening, being thus deflected outwards into the organ when said balloon is inflated by injecting a fluid through a second side channel and third opening, whereby the outwardly deflected ends of said thermocouples come into tangential engagement with a wall of the organ irradiated by said antenna.

3. A radiating device including a catheter provided at its distal end with an inflatable balloon and adapted to receive multiple injected liquid fluid flows passing therethrough, a radiofrequency radiating antenna and multiple thermocouples, the radiating antenna being submerged within a fluid flow, characterized in that

said radiating antenna is submerged within a flow which proceeds through a central channel surrounding said radiating antenna towards the distal end of said catheter and passes from said catheter through a first opening into an organ to be treated, while flowing back into said catheter towards the proximal end thereof through a second separate opening of a side channel surrounding the power supply cables of said thermocouples,

the ends of said thermocouples project out of said second opening, being thus deflected outwards into the organ when said balloon is inflated by injecting a fluid through a second side

channel and third opening, whereby the outwardly deflected ends of said thermocouples come into engagement with a wall of the organ irradiated by said antenna.

4. A radiating device for irradiating an organ comprising:

a catheter provided with an inflatable balloon and including a central channel, first and second side channels, and first, second, and third openings;

an antenna, situated at a first end portion of the catheter, the antenna being submerged in a first fluid that flows through the central channel surrounding the antenna towards the first end portion of the catheter, passes from the catheter through the first opening, and flows back into the catheter towards a second end portion thereof through the second opening; and

a plurality of thermocouples, having ends, the plurality of thermocouples extending along the first side channel of the catheter, each of the ends of the plurality of thermocouples projecting out of the second opening and being deflected outwards when the balloon is inflated by injecting a second fluid through the second side channel and the third opening,

wherein the deflected ends of the plurality of thermocouples contact a wall of the organ irradiated by the antenna.

5. A radiating device for irradiating an organ comprising:

a catheter provided with an inflatable balloon and including first and second channels and a first opening;

an antenna, situated at an end portion of the catheter, the antenna being submerged in a fluid that flows through the first channel surrounding the antenna and into the organ; and

a plurality of thermocouples, having ends, the plurality of thermocouples extending along the second channel, each of the ends of the plurality of thermocouples projecting out of the first opening and being deflected outwards when the balloon is inflated,

wherein the deflected ends of the plurality of thermocouples contact a wall of the hollow organ irradiated by the antenna.

6. A radiating device for irradiating an organ comprising:

a catheter provided with an inflatable balloon;

an antenna, situated at an end portion of the catheter, for irradiating the organ;

a channel for providing a fluid to the organ; and

a plurality of thermocouples, having ends, the plurality of thermocouples extending along the catheter, each of the ends of the plurality of thermocouples being deflected outwards when the balloon is inflated,

wherein the deflected ends of the plurality of thermocouples contact a wall of the organ irradiated by the antenna.

7. A radiating device for irradiating an organ comprising:

a catheter provided with an inflatable balloon and including first and second channels and a first opening;

an antenna, situated at an end portion of the catheter, the antenna being submerged in a fluid that flows through the first channel surrounding the antenna and into the organ; and

a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices being deflected outwards when the balloon is inflated,

wherein the deflected ends of the plurality of temperature sensing devices contact a wall of the organ irradiated by the antenna.

8. A radiating device for irradiating an organ comprising:

a catheter provided with an inflatable balloon;

an antenna, situated at an end portion of the catheter, for irradiating the organ;

a channel for providing a fluid to the organ; and

a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices being deflected outwards when the balloon is inflated,

wherein the deflected ends of the plurality of temperature sensing devices contact a wall of the organ irradiated by the antenna.

9. A radiating device for irradiating an organ comprising:

a catheter;

an antenna, situated at an end portion of the catheter, for irradiating the organ;

a channel, within the catheter, for providing a fluid comprising a cytotoxic substance to the organ; and

a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices being deflected outwards after the catheter is inserted into the organ,

wherein the deflected ends of the plurality of temperature sensing devices contact a wall of the organ irradiated by the antenna.

10. A radiating device for irradiating an organ comprising:

a catheter, including a channel for providing a fluid to the organ;

an antenna, situated at an end portion of the catheter, for irradiating the organ; and

a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices being deflected outwards after the catheter is inserted into the organ,

wherein the deflected ends of the plurality of temperature sensing devices contact a wall of the organ irradiated by the antenna.

11. A radiating device for irradiating a cavity comprising:

a catheter;

an antenna, situated at an end portion of the catheter, for irradiating the cavity;

a channel for providing fluid to the cavity; and

a plurality of temperature sensing devices, having ends, the plurality of temperature sensing devices extending along the catheter, each of the ends of the plurality of temperature sensing devices being deflected outwards after the catheter is inserted into the cavity,

wherein the deflected ends of the plurality of temperature sensing devices contact a wall of the cavity irradiated by the antenna.

12. The radiating device as recited in claim 11, wherein the channel is within the catheter.

13. The radiating device as recited in claim 12, wherein the antenna is within the channel.

14. The radiating device as recited in claim 13, wherein the fluid flows by the antenna and into the cavity.

15. The radiating device as recited in claim 11, further comprising a shielded cable coupled to the antenna.

16. The radiating device as recited in claim 15, wherein the fluid flows by the shielded cable and the antenna and into the cavity.

17. The radiating device as recited in claim 11, further comprising means for providing a second fluid around the antenna.

18. The radiating device as recited in claim 11, wherein the fluid comprises a conditioning liquid.

19. The radiating device as recited in claim 11, wherein the fluid comprises a solution of a selective cytotoxicity substance.

20. The radiating device as recited in claim 11, wherein a frequency range of the antenna is 900-1000 MHz.

21. The radiating device according to claim 11, wherein the antenna comprises a linear dipole antenna.

22. The radiating device according to claim 21, wherein the linear dipole antenna comprises a coil-shaped segment and a linear conductor.

23. The radiating device according to claim 22, further comprising:

a first plastic sleeve surrounding a portion of the linear conductor;

a metal braiding surrounding the first plastic sleeve;

a second plastic sleeve surrounding the metal braiding;

a metal cylinder surrounding the second plastic sleeve and electrically coupled to the metal braiding; and

a third plastic sleeve surrounding the metal cylinder.

24. The radiating device as recited in claim 11, further comprising a stainless steel wire coupled to each of the plurality of temperature sensing devices.

25. The radiating device as recited in claim 11, further comprising means for retaining the plurality of temperature sensing devices prior to deflection.

26. The radiating device according to claim 25, wherein the retaining means comprises at least one notch.

27. The radiating device according to claim 11, further comprising a sealing member for sealing the antenna.

28. The radiating device according to claim 27, further comprising a sealing member for each of the plurality of temperature sensing devices.

29. The radiating device according to claim 27, wherein the sealing member comprises a polytetrafluoroethylene layer.

30. The radiating device according to claim 11, further comprising a second plurality of temperature sensing devices for detecting temperatures at predetermined positions along the antenna.

31. The radiating device according to claim 30, wherein each of the second plurality of temperature sensing devices is coupled to a power supply cable.

32. The radiating device according to claim 31, wherein each of the power supply cables is wound into a helical coil.

33. The radiating device according to claim 11, wherein the deflected ends of the plurality of temperature sensing devices tangentially contact the wall of the cavity.

34. The radiating device according to claim 11, wherein the catheter further comprises an inflatable balloon.

35. The radiating device according to claim 34, wherein the balloon is inflated by a second fluid.

36. The radiating device according to claim 35, wherein the second fluid is a liquid.

37. The radiating device according to claim 35, wherein the second fluid is a gas.

38. The radiating device according to claim 34, wherein the catheter comprises a second channel in communication with the balloon for providing a second fluid to inflate the balloon.

39. The radiating device according to claim 34, wherein each of the ends of the plurality of temperature sensing devices is deflected outwards when the balloon is inflated.

40. The radiating device according to claim 11, wherein the catheter comprises a first opening for providing the fluid into the cavity and a second opening allowing for circulation out of the cavity.

41. The radiating device according to claim 34, wherein the catheter comprises a first opening for providing the fluid into the cavity and a second opening allowing for circulation out of the cavity.

42. The radiating device according to claim 41, wherein the catheter comprises a third opening for providing a second fluid to inflate the balloon.

43. The radiating device according to claim 11, wherein the cavity is an organ.

44. The radiating device according to claim 11, wherein the cavity is a hollow organ.

45. The radiating device according to claim 11, wherein the cavity is a bladder.

46. The radiating device according to claim 11, further comprising means for protecting the cavity wall from excess heat from the antenna.

47. The radiating device according to claim 11, further comprising means for preventing the catheter from being displaced from the cavity.

48. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an inflatable balloon, an antenna, and a plurality of thermocouples, into an organ;

providing a supply of a first fluid such that the first fluid flows through a first channel of the catheter and circulates out a first opening in the catheter through the organ and into a second opening in the catheter and through a second channel of the catheter; and

inflating the balloon by passing a second fluid through a third channel of the catheter and out a third hole in the catheter and into the balloon, such that the plurality of thermocouples are deflected by the inflated balloon and contact a wall of the organ.

49. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an inflatable balloon, an antenna, and a plurality of temperature sensing devices, into an organ;

providing a supply of a first fluid such that the first fluid flows through a first channel of the catheter and circulates out a first opening in the catheter through the organ and into a second opening in the catheter and through a second channel of the catheter; and

inflating the balloon by passing a second fluid through a third channel of the catheter and out a third hole in the catheter and into the balloon, such that the plurality of temperature sensing devices, carried in the second channel, are deflected by the inflated balloon and contact a wall of the organ.

50. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an inflatable balloon, an antenna, and a plurality thermocouples, into an organ;

irradiating the organ by generating radiation using the antenna;

providing a supply of a fluid through the catheter and into the organ; and

inflating the balloon such that the plurality of thermocouples are deflected by the inflated balloon and contact a wall of the organ.

51. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an inflatable balloon, an antenna, and a plurality of temperature sensing devices, into an organ;

irradiating the organ by generating radiation using the antenna;

providing a supply of a fluid through the catheter and into the organ; and

inflating the balloon such that the plurality of temperature sensing devices are deflected by the inflated balloon and contact a wall of the organ.

52. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an antenna and a plurality of temperature sensing devices, into an organ;

irradiating the organ by generating radiation using the antenna;

providing a supply of a fluid comprising a cytotoxic substance through the catheter and into the organ; and

deflecting the plurality of temperature sensing devices to contact a wall of the organ.

53. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an antenna and a plurality of temperature sensing devices, into an organ;

irradiating the organ by generating radiation using the antenna;

providing a supply of a fluid through the catheter and into the organ; and

deflecting the plurality of temperature sensing devices to contact a wall of the organ.

54. A method of performing hyperthermal therapy comprising the steps of:

inserting a catheter, including an antenna and a plurality of temperature sensing devices, into a cavity;

irradiating the cavity by generating radiation using the antenna;

providing a supply of a fluid into the cavity; and

deflecting the plurality of temperature sensing devices to contact a wall of the cavity.

55. The method of performing hyperthermal therapy according to claim 54, wherein the providing step comprises the step of providing the fluid through the catheter and into the cavity.

56. The method of performing hyperthermal therapy according to claim 55, wherein the step of providing comprises the step of flowing the fluid past the antenna.

57. The method of performing hyperthermal therapy according to claim 54, wherein the fluid comprises a conditioning liquid.

58. The method of performing hyperthermal therapy according to claim 54, wherein the fluid comprises a solution of a selective cytotoxicity substance.

59. The method of performing hyperthermal therapy according to claim 54, wherein the catheter includes a balloon.

60. The method of performing hyperthermal therapy according to claim 59, further comprising the step of:

inflating the balloon such that the plurality of temperature sensing devices are deflected by the inflated balloon and contact the wall of the cavity.

61. The method of performing hyperthermal therapy according to claim 60, wherein the inflating step comprises the step of inflating the balloon with a liquid.

62. The method of performing hyperthermal therapy according to claim 60, wherein the inflating step comprises the step of inflating the balloon with a gas.

63. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a volume of the fluid in the cavity.

64. The method of performing hyperthermal therapy according to claim 54, further comprising the step of evacuating gas introduced by the providing step to prevent irradiation non-uniformities.

65. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a temperature of the fluid.

66. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a flowrate of the fluid.

67. The method of performing hyperthermal therapy according to claim 54, further comprising the step of sensing temperatures at different locations by modifying a location of the temperature sensing devices.

68. The method of performing hyperthermal therapy according to claim 54, further comprising the step of generating therapeutically active radiation using the antenna to achieve a temperature within the cavity lethal for cancer cells.

69. The method of performing hyperthermal therapy according to claim 54, further comprising sensing a temperature at various positions along the antenna with a second plurality of temperature sensing devices.

70. The method of performing hyperthermal therapy according to claim 54, further comprising sensing a temperature at various positions along the antenna and a shielded cable coupled to the antenna with a second plurality of temperature sensing devices.

71. The method of performing hyperthermal therapy according to claim 54, wherein the plurality of temperature sensing devices come into tangential contact with the wall of the cavity.

72. The method of performing hyperthermal therapy according to claim 54, wherein a second plurality of temperature sensing devices come into tangential contact with the wall of the cavity.

73. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a temperature of the wall of the cavity.

74. The method of performing hyperthermal therapy according to claim 54, further comprising the step of controlling a temperature of the antenna.

75. The method of performing hyperthermal therapy according to claim 54, wherein the inserting step comprises inserting the catheter into an organ.

76. The method of performing hyperthermal therapy according to claim 54, wherein the inserting step comprises inserting the catheter into a hollow organ.

77. The method of performing hyperthermal therapy according to claim 54, wherein the inserting step comprises inserting the catheter into a bladder.

78. The method of performing hyperthermal therapy according to claim 54, further comprising the step of protecting the cavity wall from excess heat from the antenna.

79. The method of hyperthermal therapy according to claim 54, further comprising the step of preventing the catheter from being displaced from the cavity.

ABSTRACT

A flexible three-paths catheter provided with a balloon carries a sealingly sheathed radiofrequency radiating antenna, together with the shielded power supply cable and with some thermocouples, within a plastic lining surrounded by a flow of liquid; a second path carries the power supply cables of some outer thermocouples, flooded by the reverse liquid flow, while the third path allows a fluid to flow through for inflating the balloon.

Introduction of the catheter into a hollow organ makes it possible to perform hyperthermal therapy of tumors by means of radiation.

Fig. 1

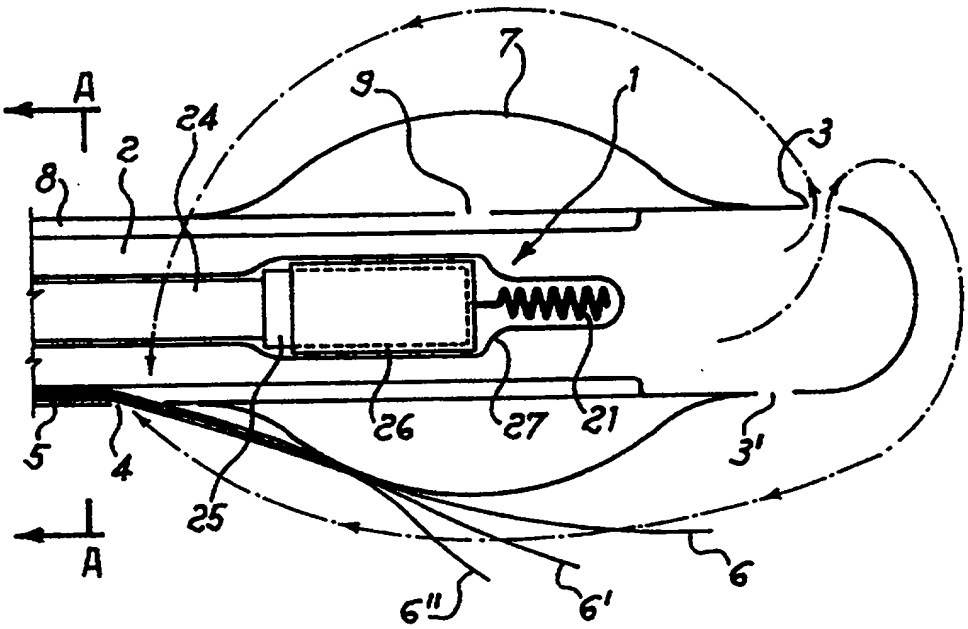


Fig. 1A

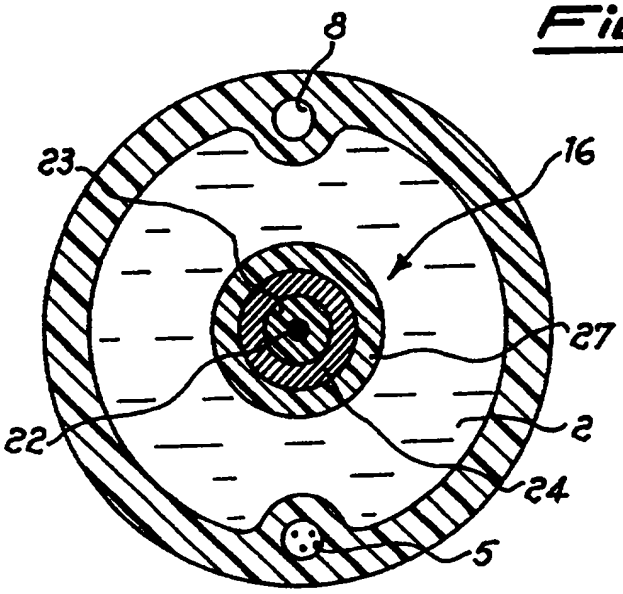


Fig. 2

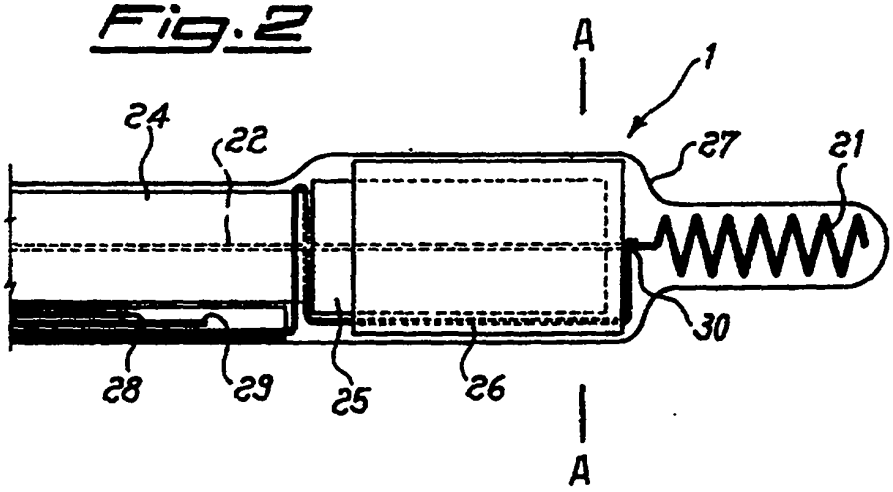
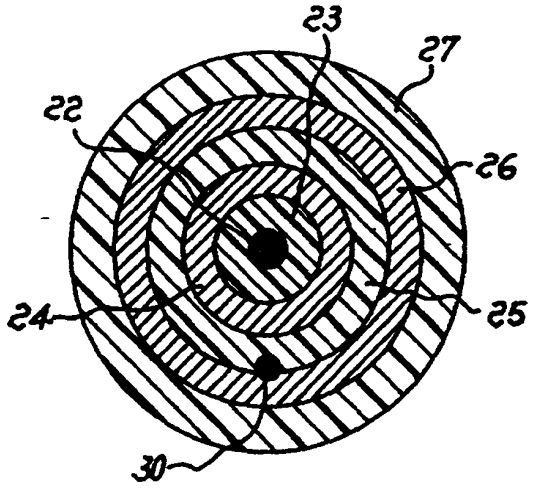
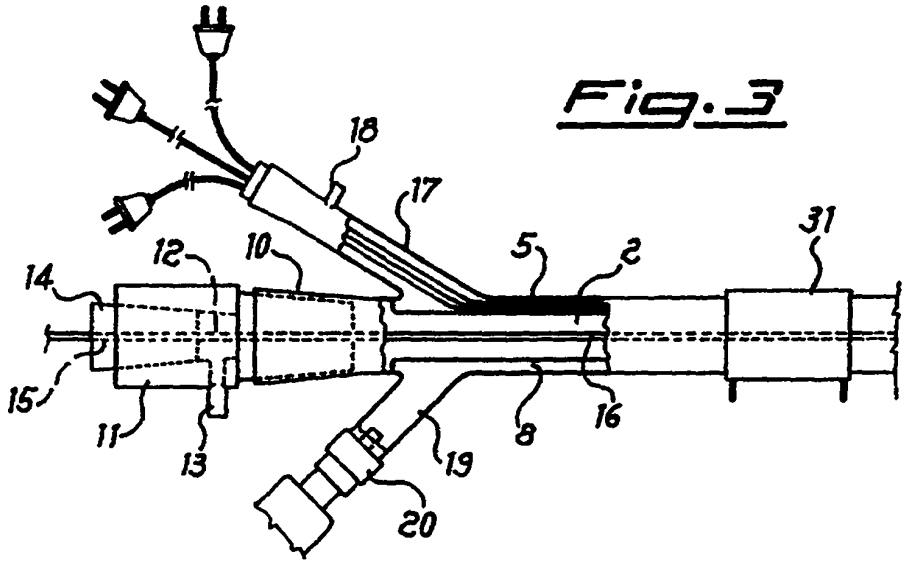


Fig. 2A




18
17
31
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19
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Fig. 3

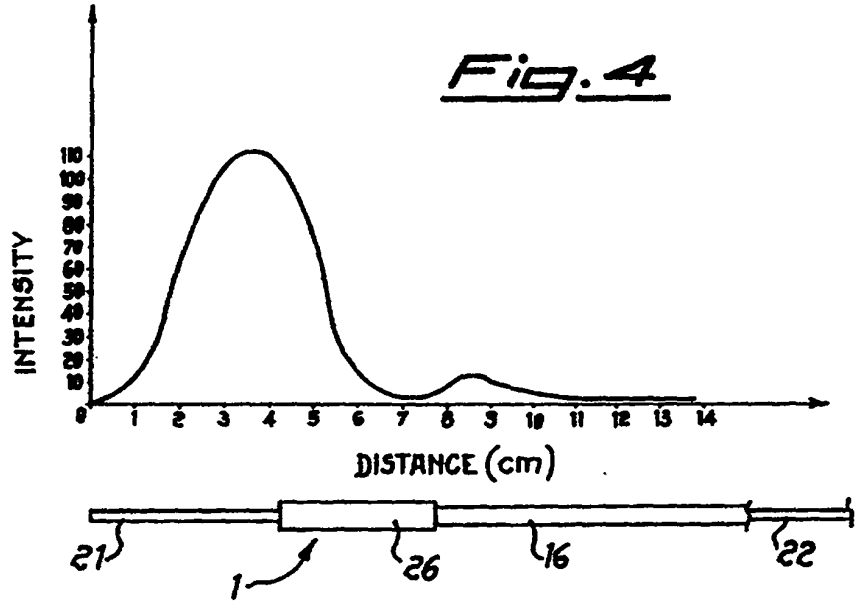

INTENSITY
0 1 2 3 4 5 6 7 8 9 10 11 12 13 14
DISTANCE (cm)
21
1
26
16
22

Fig. 4

Fig. 5

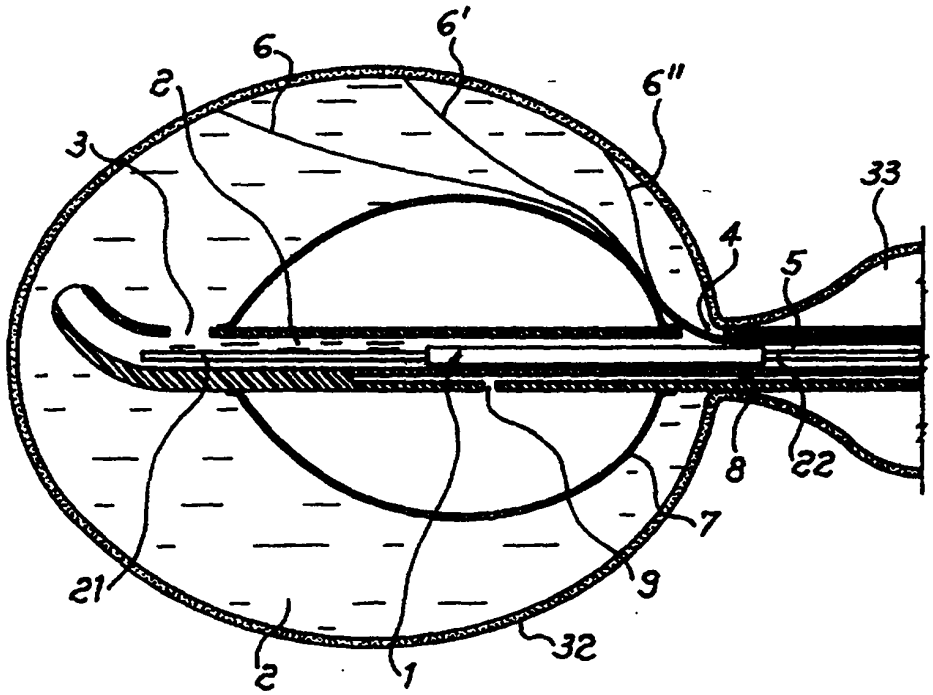
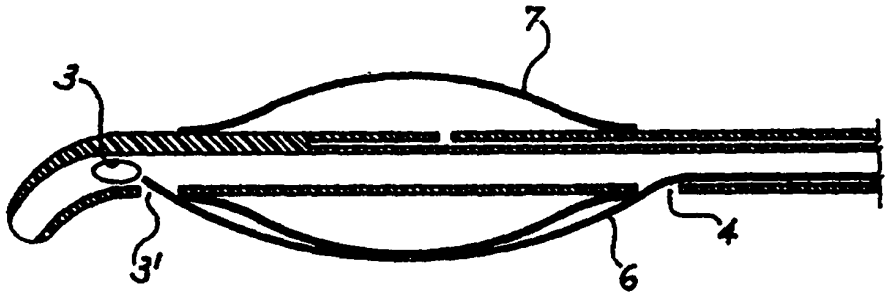


Fig. 6



#4

PATENT
Attorney Docket No. 6530.0060

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Reissue Application of:

U.S. Patent No. 5,431,648

Inventor: Avigdor Lev

Issued: July 11, 1995

Serial No.: 08/889,825

Filed: July 8, 1997

For: RADIATING DEVICE FOR HYPERTHERMIA

Group Art Unit: 3309

Examiner: Not assigned

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

DECLARATION OF AVIGDOR LEV

I, Avigdor Lev, hereby declare that:

1. My residence, post office address and citizenship are as stated below under my name.

2. I believe I am the original, first and sole inventor of the subject matter that is claimed in U.S. Patent No. 5,431,648 and in U.S. Reissue Patent Application Serial No. 08/889,825, filed on July 8, 1997.

3. I have reviewed and understand the contents of the above-identified reissue application, including the claims.

4. I acknowledge the duty to disclose information that is material to the

examination of this reissue application in accordance with Title 37, Code of Federal Regulations, § 1.56.

5. I hereby claim foreign priority benefits under Title 35, United States Code, § 119 of any foreign applications for patent or inventor's certificate or of any PCT international applications designating at least one country other than the United States of America listed below and have also identified below any foreign applications for patent or inventor's certificate or any PCT international applications designating at least one country other than the United States of America filed by me on the same subject matter having a filing date before that of the applications of which priority is claimed.

Country (if PCT indicate PCT)	Application Number	Date of Filing	Priority Claimed Under 35 U.S.C.§ 119
Italy	MI91 A 002993	November 11, 1991	[XX] Yes [ ] No
PCT	PCT/IT92/00142	November 10, 1992	[XX] Yes [ ] No

6. I believe that U.S. Patent No. 5,431,648 is partially inoperative by reason of my having claimed less than I had a right to claim. U.S. Patent No. 5,431,648 includes one (1) independent claim, claims.

Claim 1 recites a radiating device. U.S. Patent 5,431,648 does not include any method claims. At the time I filed the patent application, I did not appreciate that one of the aspects of the invention could be expressed as a method of performing hyperthermal therapy. Nevertheless, I consider such a method to be part of my invention. Accordingly, claims directed to a method of performing hyperthermal therapy are being sought in this reissue application.

7. All errors being corrected in the reissue application up to the time of filing the present Declaration arose without any deceptive intention on my part.

8. I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

A Lev Date: 4 MARCH 1998

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